EEIN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

TIMOTHY LUNCEFORD and KAREN LUNCEFORD,	§	
Plaintiffs,	§	CIVIL ACTION NO. 1:19-cv-00035
V.	§	
LIVEYON, LLC,	§	
Defendant.	§	

PLAINTIFFS' ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, TIMOTHY LUNCEFORD and KAREN LUNCEFORD, Plaintiffs, and file their Original Complaint complaining of LIVEYON, LLC, Defendant, and would respectfully show the Court the following:

1. PARTIES

1.1 This is a product liability case grounded in negligence, negligence *per se*, gross negligence and fraud.

1.2 Timothy Lunceford and Karen Lunceford are residents of Henderson County, Texas, and this District.

1.3 The Defendant is Liveyon, LLC, a Nevada corporation.

2. JURISDICTION AND VENUE

2.1 This action is brought pursuant to 28 U.S.C. §1331(a)(1) which confers original jurisdiction on the Federal District Courts in suits between citizens of different states where the amount in controversy exceeds $75,000, as it does in this case.

2.2 Venue is proper in this district pursuant to 28 U.S.C. § 1391(e)(1)(B), because a substantial part of the events or omissions giving rise to the claim occurred within this District.

3. SERVICE OF PROCESS

3.1 Defendant, LIVEYON, LLC, is a foreign corporation organized and existing under the laws of the State of Nevada, and may be served with process by serving the Texas Secretary of State at 1019 Brazos Street, Austin, Texas 78701, as its agent for service because Defendant has not designated or maintained a resident agent for service of process in Texas, as required by statute, and request is made that the Secretary of State immediately forward a duplicate copy of the process to Defendant's registered agent for service, VCORP Services, LLC, 1645 Village Center Circle, Suite 170, Las Vegas, Nevada 89134.

4. FACTS

4.1 In the summer of 2018, Plaintiff Timothy Lunceford, 52, sought treatment for back pain.

4.2 A pain management specialist attempted to treat Plaintiff with epidural steroid injections but they did not provide long-lasting relief.

4.3 After multiple discussions with his doctor, Plaintiff decided to try stem cell therapy, specifically an injection of human umbilical cord stem cells marketed and supplied by Defendant Liveyon, LLC.

4.4 Plaintiff's pain management physician had visited the Liveyon, LLC facility in California and had attended presentations by Defendant in which it had promoted the efficacy and safety of its umbilical cord stem cell product.

4.5 The presentations included representations that the product was "rigorously" tested for disease and the donors thoroughly screened, as well as representations that the product was particularly potent because each vial contained millions of live stem cells.

4.6 On July 27, 2018, at Novamed Surgery Center in Tyler, Texas, Plaintiff was injected at L4-L5 and L5-S1 with a substance purported to be umbilical cord stem cells that was obtained from Defendant Liveyon, LLC and identified as Lot No. GO12-050418,

4.7 The substance was contaminated with bacteria when Defendant Liveyon, LLC caused it to be placed in the stream of commerce.

4.8 After the procedure, Plaintiff experienced a significant amount of pain which continued to escalate so that by the second post-procedure day, July 29, 2018, Plaintiff was admitted to Texas Spine and Joint Hospital where his pain was treated unsuccessfully with medication and an epidural steroid injection.

4.9 Blood cultures obtained on August 2, 2018 were positive for *Esherichia coli* and *Enterococcus faecalis*, bacteria that live in the intestinal tracts of humans and animals.

4.10 Plaintiff was transferred to UT Health—East Texas on August 3, 2018.

4.11 Plaintiff was treated with intensive intravenous antibiotics and, on August 21, 2018, a neurosurgeon attempted to remove the infected tissue from Plaintiff's spine surgically.

4.12 Plaintiff remained hospitalized until September 24, 2018, when he was discharged on IV antibiotics and oral morphine.

4.13 After discharge from the hospital, Plaintiff required physical therapy which he obtained from Athens Physical Therapy.

4.14 Plaintiff continues to suffer from debilitating physical and emotional pain.

4.15 It is currently unknown whether the infection has been resolved completely or whether it will recur in the future.

4.16 The paid or incurred medical expenses for the treatment of Plaintiff's injuries currently exceed $350,000.

4.17 Plaintiff has been unable to perform his duties as a wildlife biologist for Briar Lake Ranch and he has incurred lost wages and has suffered a loss of wage earning capacity.

4.18 Plaintiff Linda Lunceford was required to take a leave of absence from her job at Children's Protective Services from approximately August 3 to October 9, 2018 and she has incurred lost wages as well as a loss of consortium and the value of her husband's household services.

4.19 Plaintiff was one of twelve patients reported to the Center for Disease Control who were seriously injured within the same time period by the injection or infusion of similarly-contaminated products processed by Genetech, Inc., an insolvent California corporation, and marketed and distributed by Defendant Liveyon, LLC.

4.20 The Food and Drug Administration (FDA) has promulgated extensive rules and regulations, contained in 21 CFR 1271, intended to ensure that human cells, tissues and cellular and tissue-based products (HCT/Ps) are safe.

4.21 Defendant Liveyon, LLC marketed and promoted its product for the treatment of an assortment of orthopedic ailments, such as osteoarthritis, back pain and disc pathology. The product was not marketed for homologous use and, while the product was claimed to have a systemic effect, it was not marketed for allogeneic use. Therefore, the products was required to comply with the FDA rules applicable to both drugs and biologic products.

4.21 To lawfully market such a product, the FDA requires an approved biologics license application. While in the developmental stage, the products may be used in humans only if an

investigational new drug application is in effect. Neither Liveyon nor Genetech had an approved biologics license application or investigational new drug application when the product in question was processed and introduced into the stream of commerce.

4.22 The Food and Drug Administration (FDA) has not approved the use of HCT/Ps derived from umbilical cord blood for treatment of orthopedic conditions such as Plaintiff's degenerative disc disease.

4.23 21 CFR 1271.150 (iii) required Defendant Liveyon, LLC to "ensure" that Genetech, Inc. complied with the rules prescribed in 21 CFR 1271, including rules governing donor screening and eligibility, current good manufacturing and current good tissue practices, when Defendant contracted with Genetech, Inc. to supply its product, and thereafter to monitor the practices of Genetech, Inc. and determine that all products obtained from Genetech, Inc. had been manufactured in compliance with FDA rules before distributing them.

4.24 On June 18-22, 2018, the FDA conducted an inspection of Genetech, Inc., and on June 22, 2018 reported finding a number of dangerous deficiencies in Genetech, Inc.'s donor screening, current good manufacturing and current good tissue practices that had been present since Genetech, Inc. began operations in mid-2017, which meant that Genetech, Inc. had *never* manufactured the product in accordance with FDA rules.

4.25 Defendant Liveyon LLC used Genetech, Inc. as its supplier until approximately October 10, 2018, well after several patients had been injured by its contaminated products.

5. CAUSES OF ACTION

5.1 Plaintiffs incorporate by reference the preceding paragraphs.

5.2 Paragraphs 5.3 through 5.13 list specific acts or omissions of negligence, negligence *per se*, gross negligence and fraud committed by Defendant Liveyon, LLC, through its principals,

managing agents and employees, each of which was a proximate cause of Plaintiffs' injuries and damages.

5.3 As the distributor of the substance in question, Defendant Liveyon, LLC was a "manufacturer," as that term is defined by 21 CFR 1271, and it was obligated to comply with the requirements of that regulation applicable to drugs and biologics that are intended to ensure that human cells, tissues and cellular and tissue-based products (HCT/Ps) are safe. It willfully failed to do so, despite knowledge that compliance with those regulations was essential to protect the safety and health of recipients of the product, and therefore its negligence constitutes negligence, negligence *per se* and gross negligence

5.4 Defendant Liveyon, LLC negligently marketed its product for the treatment of an assortment of orthopedic ailments, such as Plaintiff Timothy Lunceford's disc disease, despite knowing that this use was not approved for such use by the FDA.

5.5 Defendant Liveyon, LLC, marketed and distributed the product in question knowing that it did not have, and Genetech, Inc. did not have, an approved biologics license application or investigational new drug application, and this conduct constituted negligence and negligence *per se.*

5.6 Defendant Liveyon LLC knew that the requirement of an approved biologics license application and an investigational new drug application carried with them the requirement that the product comply with FDA rules and regulations promulgated in 21 CFR 1271 intended to protect the safety of the patients injected with the product, and that the failure to comply with those rules put those patients at significant risk. Therefore, Defendant's willful conduct in marketing the product constituted negligence, negligence *per se* and gross negligence

5.5 Defendant Liveyon, LLC knowingly and willfully failed to comply with the provisions of 21 CFR 1271 pertaining to donor eligibility and good tissue and manufacturing practices and such failure constituted negligence, negligence *per se* and gross negligence.

5.6 Defendant Liveyon, LLC was required by 21 CFR 1271.150 (iii) to "ensure" that Genetech, Inc. complied with the FDA rules described in 21 CFR 1271 governing donor screening and eligibility, current good manufacturing practices and current good tissue practices when Defendant contracted with Genetech, Inc. to supply its HCT/Ps, but it failed to do so, and therefore committed acts and omissions of negligence, negligence *per se* and gross negligence.

5.7 Defendant Liveyon, LLC failed to monitor the practices of Genetech, Inc. appropriately and failed to determine whether the HCT/Ps in question had been manufactured in compliance with FDA rules governing donor screening and eligibility, current good manufacturing practices and current good tissue practices prior to their distribution, as required by 21 CFR 1271.150 and therefore is liable for its negligence, gross negligence and negligence *per se.*

5.8 Defendant Liveyon, LLC knowingly continued to use Genetech, Inc. as the supplier of its HCT/Ps long after Defendant knew, or should have known, that Genetech, Inc. engaged in dangerously deficient processing practices, which was also in violation of 21 CFR 1271.150 (iii) and constituted negligence, negligence *per se* and gross negligence.

5.9 Defendant Liveyon LLC negligently failed to warn or advise purchasers and prospective purchasers of its product, and their patients, of the risks posed by Genetech, Inc.'s dangerous practices and it negligently failed to recall unused vials of its product in a timely fashion.

5.10 Defendant Liveyon, LLC negligently and fraudulently marketed the product in question as containing millions of living stem cells when, in fact, there were no viable cells by the time the substance was injected into the patient. This representation was material, because without viable

cells, the substance was not "stem cells," at all; it was made with the intention that it be believed and relied upon by physicians and patients; and it was believed and relied upon by Plaintiff and his physician.

5.11 Defendant Liveyon, LLC negligently represented that the HCT/Ps in question had been rigorously tested for contamination when it knew or should have known that the product was not tested according to the mandatory FDA requirements described above.

5.12 Defendant Liveyon, LLC negligently promoted its HCT/Ps as being effective for the treatment of lumbar disc disease when it knew, or should have known, that there was no valid scientific evidence establishing the efficacy of the specific material that it was marketing for such use.

5.13 Each of the forgoing acts or omissions was a proximate cause of Plaintiffs' injuries and damages.

5.14 Plaintiffs reserve the right to seek leave to amend this Complaint after a reasonable time for discovery to expand or adjust the allegations of negligence made herein.

6. DAMAGES

6.1 Plaintiffs incorporate by reference the preceding paragraphs.

6.2 Plaintiff Timothy Lunceford has incurred the following elements of damages:

A. Physical pain;

B. Mental anguish;

C. Physical impairment;

D. Reasonable and necessary medical, custodial, attendant care, rehabilitative, and other costs and

E. Lost wages.

6.3 Plaintiff Timothy Lunceford will incur the following elements of damages in the future, beyond the time of trial of this case.

A. Physical pain;

B. Mental anguish;

C. Physical impairment;

D. Reasonable and necessary medical, custodial, attendant care, rehabilitative, and other costs; and

E. Lost wages and wage-earning capacity.

6.4 Plaintiff Linda Lunceford has incurred the following elements of damages:

A. Mental anguish;

B. Loss of consortium;

C. Lost wages; and

D. Loss of her husband's household services.

6.5 Plaintiffs also seek recovery of both pre-judgment and post-judgment interest at the maximum rate allowed by law.

7. EXEMPLARY DAMAGES

7.1 Plaintiffs incorporate by reference the preceding paragraphs.

7.2 The conduct of Defendant Liveyon, LLC constituted gross negligence, malice and/or fraud and justifies an award of punitive or exemplary damages for which Plaintiffs bring suit.

8. AD DAMNUM AND PRAYER FOR RELIEF

8.1 Plaintiffs have been damaged and will be damaged in an amount greatly exceeded the jurisdictional minimum of this Court.

9. DEMAND FOR JURY TRIAL

9.1 Plaintiffs hereby request a trial by a jury in this case.

WHEREFORE, PREMISES CONSIDERED, the Plaintiffs request that the Defendant be cited to appear and answer herein; that upon final trial and hearing hereof, the Plaintiffs have judgment against the Defendant, for actual damages, pre-judgment and post-judgment interest at the applicable legal rate, and for such other and further relief, at law and in equity, both general and special, the Court deems appropriate and to which the Plaintiffs may be entitled.

Respectfully submitted,

HAMPTON AND KING

BY: ____/s/ *Hartley Hampton*_____

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